McCarter & English

Cynthia S. Betz
Associate
T. 973-848-5377
F. 973-297-6636
cbetz@mccarter.com

McCarter & English, LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102-4056
www.mccarter.com

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VIA ECF

Hon. José R. Almonte, U.S.M.J.
U.S. District Court for the District of New Jersey
Martin Luther King Building & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: ***Pacira Pharmaceuticals, Inc. v. eVenus Pharmaceuticals Labs., Inc.,*** **No. 2:21-cv-19829-MCA-JRA ("First Action")**
Pacira Pharmaceuticals, Inc. v. eVenus Pharmaceuticals Labs., Inc., **No. 2:23-cv-02367-MCA-JRA ("Third Action")**

Dear Judge Almonte:

We, along with Fish & Richardson P.C., Perkins Coie LLP, and O'Toole Scrivo, LLC, represent Plaintiffs in these matters and are writing to request consolidation as both cases concern whether eVenus's proposed ANDA products infringe Pacira's patents covering its blockbuster drug EXPAREL®, a non-opioid analgesic for pain management. Defendants oppose the request.

I. eVenus Refused to Agree to Add the '348 Patent to the First Action After Serving Its PIV Notice Necessitating the Third Action

Pacira filed a Hatch-Waxman patent infringement suit against Defendants eVenus and Jiangsu Hengrui in this Court on November 8, 2021, alleging infringement of U.S. Patent No. 11,033,495 ("the '495 patent").[1] That First Action arose out of eVenus's submission of an Abbreviated New Drug Application (ANDA) to the FDA seeking approval to commercially manufacture, use, offer for sale, sell and/or import a purported generic version of EXPAREL® bupivacaine liposome injectable suspension, 266 mg/20 mL (13.3 mg/mL) approved in NDA No. 022496, and Plaintiffs' receipt of a Notification of Paragraph IV Certification from eVenus on the '495 patent ("the September eVenus Notice Letter").[2]

[1] *Pacira Pharmaceuticals, Inc. v. eVenus Pharmaceuticals Laboratories, Inc.*, No. 2:21-cv-19829-MCA-JRA ("the First Action").

[2] Pacira refers to certain Notice Letters, but has not included them with this correspondence. Pacira will provide copies to the Court upon request.

After Plaintiffs filed the First Action, they received a second Notification of Paragraph IV Certification from eVenus on or around December 28, 2021 ("the December eVenus Notice Letter"), this time disclosing that the ANDA had been amended to seek approval to commercially manufacture, use, offer for sale, sell and/or import purported generic versions of both the 266 mg/20 mL version and 133 mg/10 mL version of EXPAREL® bupivacaine liposome injectable suspension, approved in NDA No. 022496, and certifying as to both the '495 patent and U.S. Patent No. 11,179,336 ("the '336 patent").

On February 10, 2022, Plaintiffs filed a second patent lawsuit asserting both the '495 patent and '336 patent against Defendants eVenus and Jiangsu Hengrui.[3] Plaintiffs subsequently amended the complaints in both the First and Second Actions to add Defendant Fresenius Kabi, and on May 9, 2022, the Court granted the parties' request to consolidate the First and Second Actions for all purposes. D.I. 85.

Fact discovery in the First Action, now the lead case, remains open and is still in relatively early stages; no fact depositions have occurred. The Court held a *Markman* hearing on March 9, 2023, but has not yet issued a claim construction order. The thirty-month stay expires April 1, 2024, for the 266 mg/20 mL ANDA product and July 1, 2024, for the 133 mg/10 mL ANDA product. When the parties jointly proposed an extension to the case schedule, the proposal set the Final Pretrial Conference for November 17, 2023, in the event the Court elected not to move the target December 2023 trial date. D.I. 158. The Court So Ordered the proposed extension of all deadlines through the Final Pretrial Bench Conference, D.I. 158, and recently moved the trial to February 6, 2024. D.I. 178. This leaves a nearly three-month window between the Final Pretrial Conference and trial that could be re-allocated to pre-trial deadlines. As part of the extension to the case schedule, Defendants have agreed not to launch any of its proposed ANDA products before July 1, 2024. D.I. 158.

On or around April 17, 2023, Defendants served a Notification of Paragraph IV Certification ("the April eVenus Notice Letter") regarding, *inter alia*, U.S. Patent No. 11,426,348 ("the '348 patent"), which issued on August 30, 2022, and was listed in the FDA's Orange Book in connection with EXPAREL® since September 2, 2022. The '348 patent shares a specification with the '495 and '336 patents, and like the '336 patent, claims priority to the application from which the '495 patent issued. And like the '495 and '336 patents, the '348 patent is directed to the scaled-up manufacture of EXPAREL®.

[3] *Pacira Pharmaceuticals, Inc. v. eVenus Pharmaceuticals Laboratories, Inc.*, No. 2:22-cv-00718 ("the Second Action").

Defendants' primary non-infringement argument as set forth in the December eVenus Notice Letter for the '336 patent is that eVenus's Proposed ANDA Products do not meet the limitation "wherein the plurality of internal aqueous chambers of the MVLs has a pH of about 5.5." The independent claims of the '348 patent do not recite a similar limitation. Defendants' primary non-infringement argument as set forth in the September and December eVenus Notice Letters for the '495 patent relates to certain mixing speeds used for manufacturing the EXPAREL® compositions. The independent claims of the '348 patent do not recite a limitation for mixing speeds.

On the same day that Defendants served the April eVenus Notice Letter—April 17—the parties met and conferred regarding whether Defendants would oppose a motion from Pacira for leave to file a second amended complaint to assert the '348 patent. Following the meet and confer, at Defendants' request, Pacira shared in writing its position on a number of issues: 1) Pacira stated that, in its view, none of the '348 patent terms required claim construction; 2) Pacira proposed a schedule to complete exchange of contentions by June 16; 3) Pacira agreed to assert no more than 15 claims from the '348 patent; 4) Pacira agreed not to add any other patents to the case; and 5) Pacira promised to continue to meet and confer to amend the overcall case schedule as necessary.

In response, Defendants requested Pacira give Defendants a covenant not to sue on the remainder of Pacira's patent portfolio covering EXPAREL®, including those patents not yet issued. Defendants further requested Pacira agree to reverse the order of the Court's Local Rules concerning contention exchanges so that Pacira would serve infringement contentions before Defendants served non-infringement and invalidity contentions. Finally, Defendants requested Pacira identify its understanding of the English word "consistently" that appears in the '348 patent claims.

On April 24, Pacira sent Defendants a draft second amended complaint. Given that unasserted patents have no relation to issue of amendment, Pacira declined to give a covenant not to sue and reiterated its previously-expressed view that the English word "consistently" does not require claim construction proceedings. As for exchanging contentions, Pacira offered to provide an identification of asserted claims within two business days of Defendants' written consent to amendment, which would provide about an extra week for Defendants to prepare invalidity and non-infringement contentions. Pacira also offered to entertain an alternative schedule.

On April 26, without explanation, Defendants notified Pacira that they would oppose a motion for leave to file a second amended complaint to add the '348 patent.

Pacira filed the Third Action asserting the ’348 patent on April 28, 2023. While at the May 8 conference Defendants suggested that it was untoward for Pacira to file a separate case as opposed to seeking leave to amend, Pacira’s chosen strategy is just a matter of efficiency. Resolution of the parties’ disputes around the ’348 patent would be delayed if Pacira did not file its complaint until after Pacira’s motion to amend was potentially denied. On May 5, Pacira wrote Defendants and explained its bases for consolidation, and, to get the contentions process moving, identified the claims of the ’348 patent that it is going to assert.

On May 11, 2023 the parties met and conferred to discuss Pacira’s proposal that the parties jointly move to consolidate the Third Action with the First Action. Discussions focused on three issues. First, Defendants requested Pacira give Defendants a covenant not to sue on the patents listed in the Orange Book as covering EXPAREL® as well as any patents that may issue from currently pending patent applications. Pacira declined, again because unasserted patents do not impact the efficiency benefit of consolidating the ’348 patent. Second, Defendants demanded that Pacira provide a claim construction for the term “consistently.” Pacira disagreed that an explicit construction was appropriate or even helpful for the fact-finder. In the absence of clear disclaimer or lexicography, the term should be given its plain and ordinary meaning. Third, Defendants asked if Pacira would agree that discovery produced in the First Action would be deemed produced in the Third Action. Recognizing the near complete overlap of discovery between the First and Third Action, Pacira agreed. On May 16, 2023, Pacira reiterated to Defendants that Pacira remains open to working together on a schedule that would accommodate consolidation, especially in light of the Court’s new trial date. In response, Defendants declined to consent to a motion to consolidate.

II. The Parties and Court Would Save Time and Effort Litigating Questions of Law and Fact Common to Both Cases at Once

“Rule 42(a) gives the district court broad powers to consolidate actions involving common questions of law or fact if, in its discretion, such consolidation would facilitate the administration of justice.” *Borough of Edgewater v. Waterside Constr., LLC*, No. CV 14-5060 (JMV), 2017 WL 1758062, at *2 (D.N.J. May 3, 2017).

In both cases, the parties will litigate the fact issues underlying the ultimate legal issue of whether eVenus’s proposed ANDA products infringe a Pacira patent. Comparing representative claims of the ’336 patent asserted in the First Action and the ’348 patent asserted in the instant actions illustrates the common questions of fact:

Claims 1, 7, and 10 of the '336 patent asserted in the First Action	**Claims 1, 2, and 13 of the '348 patent asserted in the Third Action**
1. (a) A composition of bupivacaine encapsulated multivesicular liposomes (MVLs), comprising: (b) bupivacaine residing inside a plurality of internal aqueous chambers of the MVLs separated by lipid membranes wherein the lipid membranes comprising 1, 2-dieru-coylphosphatidylcholine (DEPC), 1, 2-dipalmitoyl-sn-glycero-3 phospho-rac-(1-glycerol) (DPPG), and at least one neutral lipid, (c) the plurality of internal aqueous chambers of the MVLs also comprise lysine; (d) and an aqueous medium in which the bupivacaine encapsulated MVLs are suspended; (e) wherein the plurality of internal aqueous chambers of the MVLs has a pH of about 5.5; (f) wherein the bupivacaine concentration in the composition is from about 11.3 mg/mL to about 17.0 mg/mL, (g) wherein erucic acid concentration in the composition is about 23 µg/mL or less after the composition is stored at 25ºC for one month, and wherein the composition has a shelf life of about 2 years when stored at 2-8ºC.	1. (a) Batches comprising compositions of bupivacaine multivesicular liposomes (MVLs), comprising: (b) bupivacaine residing inside a plurality of internal aqueous chambers of the MVLs separated by lipid membranes wherein the lipid membranes comprising 1, 2-dieru-coylphosphatidylcholine (DEPC), 1, 2-dipalmitoyl-sn-glycero-3 phospho-rac-(1-glycerol) (DPPG), and at least one neutral lipid, and (c) an aqueous medium in which the bupivacaine encapsulated MVLs are suspended; (d) wherein the batches consistently comprise an erucic acid concentration of less than about 109 µg/mL after the compositions are stored at 25ºC for six months.

7. The composition of claim 1, wherein the erucic acid concentration in the composition is about 99 µg/mL or less after the composition is stored at 25ºC for six months.	2. The batches of claim 1, wherein the batches comprise the erucic acid concentration of about 99 µg/mL or less after the compositions are stored at 25ºC for six months.
10. The composition of claim 1, wherein the encapsulated lysine concentration in the bupivacaine encapsulated MVLs composition is about 0.030 mg/mL to about 0.032 mg/mL.	13. The batches of claim 1, wherein the internal aqueous chambers of the MVLs comprise lysine, and the encapsulated lysine concentration in the bupivacaine encapsulated MVLs compositions is about 0.03 mg/mL.

The ’336 patent in the First Action and the ’348 patent in the Third Action require the Court to make findings of fact regarding whether eVenus’s proposed ANDA products meet the limitations for a) the composition of lipid membranes separating the MVLs containing bupivacaine (claim limitation 1(a) of the ’336 and ’348 patents, highlighted yellow); b) the concentration of lysine inside the internal aqueous chambers of the MVLs (claims 1(c), 10 of the ’336 patent and claim 13 of the ’348 patent, highlighted blue); the suspension of bupivacaine encapsulated MVLs in an aqueous medium (claim 1(d) of the ’336 patent and claim 1(c) of the ’348 patent, highlighted grey); and the erucic acid concentration after the compositions are stored at 25ºC for six months (claim 7 of the ’336 patent and claim 2 of the ’348 patent, highlighted green). All of the above fact issues go to the ultimate issue of infringement.

As for invalidity, eVenus’s primary invalidity argument for the ’336 patent and ’348 patent is that the claims are obvious in view of the prior art. *See* the December eVenus Notice Letter at 51; the April eVenus Notice Letter at 149. Six of the eight prior art references that eVenus contends render the ’336 patent obvious also allegedly invalidate the ’348 patent. *Compare* the December eVenus Notice Letter at 51-61 *with* the April eVenus Notice Letter at 149. Thus the ’336 patent fact issues regarding scope and content of the prior art nearly completely overlap with the fact issues for the ’348 patent on alleged obviousness.

III. The Time and Effort Saved Through Consolidation Far Outweighs the Potential for New Delays or Prejudice

In considering whether to consolidate, courts consider whether the saving of time and effort outweighs the potential for new delays, expense, confusion, or prejudice. *Re: Shire LLC v. Watson Labs., Inc.*, No. 12-cv-83 (SRC)(MAS), 2012 WL 12902495, at *2 (D.N.J. June 20, 2012). The majority of discovery in the First Action has yet to occur. The deadline for substantial completion of document production is not until May 26, 2023. The current outstanding requests for production and interrogatories seek information relevant to the infringement and validity issues concerning the ’348 patent. The parties’ agreement (reached at Defendants’ behest) that the discovery from the First Action be deemed produced in the Third Action underscores that the parties would save time and effort by consolidating the cases now and due to the near perfect overlap in discovery already underway in the First Action. While fact depositions have been noticed, the parties have yet to schedule one much less take one. The ’348 patent poses no fact issue that requires the parties to depose a witness other than those that would be noticed in the First Action. And the issues are far from set in the First Action; Defendants have filed a (consented-to) motion to amend their non-infringement contentions. Given that most of the discovery work lies ahead and that the ’348 patent does not significantly increase the workload, the saving of time and effort outweighs the minimal prejudice of adding no more than fifteen claims to the case.

To address Defendants’ concern that consolidating the cases would introduce delay, Pacira has identified the ’348 patent claims it will assert and proposed a schedule for the parties to exchange contentions within six weeks. Due to the near three-month gap between the Final Pretrial Conference and the newly set February 4, 2024 trial date, the parties could adjust the schedule to allow to extend fact discovery and the subsequent deadlines leading up to the February trial date by a few weeks to allow for the parties to exchange contentions. The minor delay is far outweighed by the time the Court would spend trying an entirely separate case on the ’348 patent from start to finish.

The only other potential for delay stems from claim construction. The Court held a claim construction hearing in the First Action on March 9, 2023. D.I. 144. Defendants have identified a single term from the ’348 patent that they believe requires the Court’s attention: “wherein the batches ***consistently*** comprise an erucic acid concentration of less sthan about 109 µg/mL.” Specifically, Defendants intend to advance the invalidity argument that the term is indefinite. *See* the April eVenus Notice Letter at 171. Rather than contending that the term has no meaning, Defendants contend that the term lacks objective scope. *Id.* Deciding whether a person of ordinary skill in the art would understand the scope of the term based on the specification is an inquiry that would benefit from a developed record. *See Cipher Pharms. Inc. v. Actavis Labs. FL, Inc.*, 99 F.Supp.3d 508, 514 (D.N.J. 2015) (opting to rule indefiniteness at summary judgment “on a more developed record” where the issue was whether a person of ordinary skill in the art would know if “about 1%” included “0.9%? 0.85%? 0.5%? etc.”). The Court need not hold a second *Markman* hearing to decide this issue as it is more properly deferred to summary judgment or, perhaps more appropriately, trial. *See Sun Pharma Global FZE v. Lupid Ltd.*, No. 18-cv-2213 (FLW), 2021 WL

4473411, at *11-13 (D.N.J. Sept. 30, 2021) (ruling on indefiniteness defense at bench trial; opinion vacated due to settlement); *Exela Pharma Scis., LLC v. Eton Pharms., Inc.*, No. 1:20-cv-00365-MN, 2022 WL 3278735, at *22-23 (D. Del. Aug. 8, 2022) (explaining that the court construed three terms at trial and rejected the indefiniteness defense asserted for two of the terms).

IV. Conclusion

Because consolidation would allow the Court and the parties to litigate questions of fact and law common to both cases, promoting efficiencies for both the Court and the parties, and because Pacira can minimize the risk of delay or prejudice to eVenus, Pacira respectfully requests the Court consolidate the Third Action into the First Action.

After a meet and confer on the issue, the parties are not in agreement and Defendants do not join in this request. Should the Court desire a formal motion, Pacira respectfully requests Your Honor order an expedited briefing schedule, with Pacira's opening brief due one week from Your Honor's order, opposition brief a week later, and a reply three days after that.

We appreciate Your Honor's attention to this matter.

Respectfully submitted,

/s/ Cynthia S. Betz

Cynthia S. Betz

cc: All counsel of record (via ECF)